UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: *United States of America, ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, CIVIL ACTION NO. 06–CV-11337-PBS *United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al.*, CIVIL ACTION NO. 05-11084-PBS *United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, Inc., et al.,* CIVIL ACTION NO. 07-10248-PBS	)	Hon. Patti B. Saris

UNITED STATES' COMMON MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO THE DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

STATUTES

Fraud Enforcement and Recovery Act of 2009:

RULES & REGULATIONS

MISCELLANEOUS

INTRODUCTION

This brief sets forth legal and factual analyses common to the plaintiffs' oppositions and cross-motions for summary judgment recently filed in the above-captioned cases.

The United States is moving for partial summary judgment against Roxane Laboratories, Inc., and Roxane Laboratories, Inc., n/k/a Boehringer Ingelheim Roxane, Inc. (collectively, "Roxane"); Dey, Inc., Dey L.P., Inc., and Dey L.P. (collectively "Dey"); and Abbott Laboratories, Inc. ("Abbott") (collectively, defendants) on three elements of its False Claims Act (FCA) claims: (1) that defendants presented and/or caused to be presented false claims to the Medicare and Medicaid programs and/or made false statements material to such claims for payment, (2) that defendants' false statements were material to the false Medicare and Medicaid claims, and (3) defendants did so knowingly as defined in the FCA. In addition, the United States is moving for summary judgment on several of defendants' affirmative defenses.[1]

The defendants in the three cases brought by the federal government for drug pricing fraud have all moved for summary judgment or partial summary judgment on a variety of issues. Defendants raise several common issues that will be addressed in this brief: (1) government knowledge, (2) statute of limitations, (3) damages, and (4) due process defenses.

I. SUMMARY JUDGMENT STANDARD

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.' " *Barbour v. Dynamics Research Corp*., 63 F.3d 32, 36-37 (1st Cir. 1995) (*quoting* Fed.

[1] Relator joins in those motions.

R. Civ. P. 56(c)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). "Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party, who 'may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial.'" *Barbour*, 63 F.3d at 37 (*quoting Anderson v. Liberty Lobby, Inc.*, 477 U. S. 242, 256 (1986)). The opposing party must show "sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50. The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." *Barbour*, 63 F.3d at 36.

II. THE FALSE CLAIMS ACT

The United States alleges that defendants violated the FCA, specifically that as a result of their false price reporting they:

(a) "knowingly" presented or caused to be presented "a false or fraudulent claim" for payment or approval in violation of 31 U.S.C. § 3729(a)(1); and

(b) "knowingly" made, used or caused to be made or used "a false record or statement" material to a "false or fraudulent claim" in violation of 31 U.S.C. § 3729(a)(1)(B);[2]

[2]The FCA was recently amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (FERA), enacted May 20, 2009. Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to this case by virtue of Section 4(f) of FERA, while Section 3729(a)(1) of the statute prior to FERA remains applicable here. "The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1) of title 31, United States Code, as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 et seq.) that are pending on or after that date . . . ." FERA, section 4(f).

As this Court has correctly noted, to establish liability under 31 U.S.C. § 3729(a)(1), the United States must prove: a) The defendants caused to be presented to the government a claim for payment; b) The claim was false or fraudulent; c) The defendants knew that the claim was false or fraudulent; and d) The false aspect of the claim was material. *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 139 (D. Mass. 2008).

A. Falsity Under The False Claims Act

This Court has consistently held that Average Wholesale Prices ("AWPs") and Wholesale Acquisition Cost ("WAC") prices that have no relationship to the actual prices paid by defendants' customers are false. *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, 103, 105-08 (D. Mass. 2007); *In re Pharm. Indus. Average Wholesale Price Litig*, 520 F. Supp. 2d 267, 270 (D. Mass 2008). The Court also has recognized the government's objective of paying provider drug ingredient cost and concluded that drug prices which "cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs . . . are by their very nature fraudulent." *In re Pharm. Indus. Average Wholesale Price Litig*, 478 F. Supp. 2d 164, 174 (D. Mass. 2007). In so doing, this Court rejected defense arguments that AWP was a "term of art" that simply meant any price published in a compendia. *Id*. at 286-87. Notably, the Court noted in its opinion that:

> In this case, in its 1991 regulations, DHS based payment for a branded drug on the lower of "estimated acquisition cost" or the "national average wholesale price" of the drug; "estimated acquisition costs" were "determined based on surveys of actual invoice prices paid by the providers furnishing the drug." 56 Fed.Reg. at 59,507. Presumably, the policy here is to ensure that the government gets the benefit of rebates and discounts, by getting lower prices. Interpreting "average wholesale price" as a retail sticker price that does not account for rebates and

> discounts would be inconsistent with the policy of having the government pay the lower of these two rates. Therefore, the Court construes "average wholesale price" in the 1998 Medicare statute to include discounts and rebates.

In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d, 285, 287 (D. Mass. 2006). The falsity of these prices establishes the falsity of both the claims submitted for reimbursement of defendants' drugs and the statements made by defendants in support of those claims.

The claims submitted to the Medicaid and Medicare programs for defendants' drugs were false because they sought reimbursement to which the claimants were not entitled. The FCA "was intended to reach all types of fraud, without qualification, that might result in a financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1986); *United States ex rel. Hendow v. Univ. of Phoenix,* No. 04-16247, 2006 WL 2530394 at *3 (9th Cir. Sept. 5, 2006) (noting that "Congress emphasized that the scope of false or fraudulent claims should be broadly construed."); *see also Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003). "'[T]he [FCA] is violated not only by a person who makes a false statement or a false record, . . . but also by one who engages in a fraudulent course of conduct that causes the government' to lose money by honoring a false claim." *United States v. Raymond & Whitecomb Co.*, 53 F. Supp. 2d 436, 445 (S.D.N.Y. 1999) (citation omitted).

Under a "fraudulent course of conduct" theory, FCA liability reaches claims submitted to the United States when there was fraud underlying a contract, benefit or status that resulted in the presentment of a claim for payment. *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999). In *Parke-Davis*, this Court found that FCA liability could lie where the defendant drug company engaged in a fraudulent course of conduct through its misleading off-label marketing promotion and that conduct led to the submission of claims to the

United States that were ineligible for payment under the Medicaid program. *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 (D. Mass. Aug. 22, 2003).

Moreover, it is well established that claim need not be "false" on its face in order for FCA liability to attach. Indeed, as this Court recently noted, "where a claim for payment is the result of a fraudulent process - bid rigging, self-dealing, etc.- such that the reliability and trustworthiness of a claim is compromised, the claim may be considered false under the FCA despite its facial accuracy." *United States v. Dynamics Research Corp.*, No. 03cv11965-NG, 2008 WL 886035, at *10 (D. Mass. March 31, 2008).

The inflated drug prices reported by defendants to the drug pricing compendia also constitute false statements material to claims for payment in violation of 31 U.S.C. § 3729(a)(1)(B). As described in detail in the defendant-specific briefs, each defendant reported prices to the price compendia relied upon by the Medicare and Medicaid programs to set payment levels for each of the defendants' drugs. The price statements were false for the same reasons set forth above, *viz.,* they were unmoored to actual transaction prices and created megaspreads and inflated government payments for the subject drugs.

B. Presentment Under the False Claims Act

The FCA "attaches 'liability upon *presentment* of a false or fraudulent claim, rather than *actual payment* on that claim.'" *Mylan Labs*., 608 F. Supp. 2d at 147, quoting *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F. 3d 428, 445-46 (6th Cir. 2005) (emphasis in original); 31 U.S.C. § 3729(a)(1). FCA liability also attaches to attempts to *cause* the government to pay false claims. *See United States v. Neifert-White Co.*, 390 U.S. at 233. Even in instances in which no damages are sustained by the federal government, a defendant can

be liable for civil penalties if the defendant caused fraudulent claims to be presented to the government. *See United States ex rel. Fago v. M & T Mortg. Corp*., 518 F. Supp. 2d 108 (D.D.C. 2007); *see also United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) (though the United States must prove causation to recover damages, proof of damages is not required to establish liability).

This Court has already set forth the two-part test for establishing whether a defendant caused the presentment of false claims, and applied the test to facts similar to those at hand. *See Parke-Davis*, 2003 WL 22048255. First, the Court examines whether the defendant's conduct was a "substantial factor" in causing the presentation of false claims to the Medicaid program. Second, the Court determines whether the submission of false Medicaid claims by pharmacists – and ultimately paid in part by the federal government – was a foreseeable consequence of the defendant manufacturer's conduct. *Id.* at *4. In the context of the AWP litigation, this Court already has determined that the reporting of prices not reflective of actual transaction prices – conduct not disputed by defendants – is sufficient to cause the presentment of inflated provider claims where reimbursement is calculated based on those prices. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d at 175. The Government will demonstrate in the individual-defendant briefs how the defendants caused the presentment of false claims for payment to the Medicare and Medicaid programs, and that the submission of such claims was not only foreseeable, it was the intended consequence of defendants' conduct.

C. Materiality under the False Claims Act

This Court has held that "[w]hether a false statement is material depends on whether it 'has a natural tendency to influence agency action or is capable of influencing agency action.'"

United States v. President & Fellows of Harvard College, 323 F. Supp. 2d. 151, 181-82 (D. Mass 2007)(citing *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F. 3d 908, 914 (4th Cir. 2003) (parenthetical omitted).[3] In this case, because the defendants' fraudulent course of conduct and statements affected government drug payment levels, they clearly had the natural tendency to influence – or were capable of influencing – the payment of government money for their products. As detailed below, the federal regulations and state payment methodologies utilized a "lower of" methodology, paying the lesser of various price points, including AWP. Had defendants reported truthful prices, the AWPs for their products would have been the lowest price point and the basis for payment. *See Mylan Labs.*, 608 F. Supp. 2d at 147 (explaining why providers' entry of inflated "usual and customary" charges did not insulate defendants from liability because of state's lower of methodology). Similarly for Medicare, the carriers determined reimbursement based upon a median price that in turn depended upon defendants' reported AWPs. Thus, the falsity of the claims and statements was clearly "material" under the FCA. 31 U.S.C. § 3729(a)(1) and (a)(1)(B).

D. Knowledge Under the False Claims Act

For purposes of the FCA, "knowledge" that the statement or claim was false or fraudulent means that the defendant:

1. had actual knowledge of the information;

2. acted in deliberate ignorance of the truth or falsity of the information; or

3. acted in reckless disregard of the truth or falsity of the information.

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[3] As part of FERA, Congress codified this interpretation and described materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

No specific intent to defraud is required. 31 U.S.C. § 3729(b); *United States ex rel. Loughren v. UnumProvident Corp.*, 2008 WL 4280133 *3 (D. Mass. Sept. 15, 2008). Knowledge may be established on summary judgment. *See, e.g.*, *United States ex rel. Longhi v. Lithium Power Techs., Inc*., 2009 WL 1959259 (5th Cir. 2009) (granting summary judgment to government on scienter in FCA case); *United States v. President and Fellows of Harvard College*, 323 F. Supp. 2d. at 190 (granting summary judgment to government on defendant's knowledge under the FCA).

III. SUMMARY OF THE MEDICARE AND MEDICAID PROGRAMS

A. Medicare

During the pertinent period, Medicare has covered certain drugs, including drugs used in conjunction with durable medical equipment ("DME"). (L.R. 56.1 Statement of Undisputed Material Facts Applicable to all Defendants ("US-C-SF") ¶3) Medicare Part B classifies and pays for covered drugs through a coding system called the Healthcare Common Procedure Coding System (HCPCS). Medicare assigns individual HCPCS codes for most drugs, typically starting with a "J" or "K." (US-C-SF ¶ 4) One HCPCS code, however, may cover one generic drug manufactured by a variety of manufacturers. Medicare Part B payments for covered drugs are based on the HCPCS codes. *Id.*

Medicare relies upon numerous "carriers" to process Part B claims. (US-C-SF ¶ 5). Since 1993, Medicare relies upon DME Regional Carriers (DMERCs) to process DME claims. (US-C-SF ¶ 6) During the pertinent time period, there were four DMERCs nationwide. *Id.* The claims for Dey's and Roxane's respiratory therapy drugs here were reimbursed almost exclusively as DME claims by the DMERCs. (US-C-SF ¶¶ 3, 6)

From 1993 through December 31, 1997, the DMERCS paid for Part B covered multiple source drugs based on the lower of the provider's billed charge or the median AWP of the generic forms of the drug. (US-C-SF ¶11). From January 1, 1998, through December 31, 2003, the DMERCs paid for Part B covered multiple-source drugs based on (a) the amount submitted by the provider on the claim, or (b) 95 percent of the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. (US-C-SF ¶ 12-13)

CIGNA was the DMERC for one of the Medicare regions (US-C-SF ¶ 6) and its practices illustrate how the DMERC determined the AWP of the generic sources of a drug. First, CIGNA would use the Red Book to find the products that fit within the narrative description of the pertinent HCPCS code. (US-C-SF ¶¶ 15, 16) Second, CIGNA would record the product information, including the published AWPs of the relevant drug products, in an array (or would update a pre-existing array),[4] and converted the published package AWP price in the Red Book to a per-unit price. (*Id.*) If there were only one National Drug Code (NDC) with a published AWP in the array, CIGNA would select that price as the median. If there were an odd number of NDCs in the array, CIGNA would select the middle NDC and its corresponding price. If there were an even number of NDCs in the array, CIGNA took the average of the middle two NDCs' prices to achieve a median. *(Id.* ¶ 16) That median then served as the basis for reimbursing for all drugs within the HCPCS code, regardless of manufacturer. (US-C-SF ¶ 4, 11-13)

[4]Arrays are simply lists of prices created by the carriers to identify the median price; the median price then generally becomes the amount that the Medicare carrier will allow for payment for the drugs at issue. (US-C-SF ¶ 11-13, 16)

B. Medicaid

1. Federal Medicaid Payment Regulations

The federal government, through regulations issued by the Centers for Medicare & Medicaid Services (CMS), established Medicaid drug payment policies in effect for the claims period in this case. Federal Medicaid regulations called for a state Medicaid program to pay the estimated acquisition cost (EAC) of a drug, along with a reasonable dispensing fee. 42 C.F.R. § 447.301.[5] EAC is defined in the Medicaid regulations as the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufactuerer or labeler in the package size of drug most frequently purchased by providers. 42 C.F.R. § 447.301.

All of the drugs at issue in this case are multi-source generic drugs, although Roxane marketed three of its drugs as "branded generics." During the claims period, the regulations set forth limits on how much Medicaid programs should pay for drugs:

> a) Multiple source drugs. Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed the amount that would result from the application of the specific limits established in accordance with § 447.332. If a specific limit has not been established under § 447.332, then the rule for "other drugs" set forth in paragraph (b) applies.

42 C.F.R. § 447.331(a).

For certain multiple source drugs, CMS set a Federal Upper Limit (FUL). For those multiple source drugs not subject to a FUL, Medicaid required that drug payments not exceed, in the aggregate, the EAC of the drug, plus a reasonable dispensing fee. (US-C-SF ¶ 22) Several of

[5] The citations herein are to the federal regulations governing Medicaid drug payments that were in effect prior to October 1, 2007. The vast majority of the claims at issue arose before that date.

the drugs at issue, including all of the Abbott drugs, were not subject to a FUL and thus fell under the regulatory constraints set forth in 42 C.F.R. § 447.331(b). This regulation required that payment for brand name drugs and drugs other than certain multiple source drugs must not exceed the lower of the (1) EACs plus reasonable dispensing fees established by the agency, or (2) providers' usual and customary charges to the general public. *Id*.

To ensure compliance with this general requirement, federal regulations during the operative period required a state to comprehensively describe the state agency's payment methodology for drugs. 42 C.F.R. § 447.333(a). States were required to show that, in the aggregate, Medicaid expenditures for brand and multi-source drugs were in accordance with upper limits set forth in 42 C.F.R. §§ 447.331 and 447.332 respectively. The failure to comply with these rules could result in CMS withholding federal Medicaid funding from a state. *See* 42 C.F.R. § 430.35.

2. State Medicaid Reimbursement Policies

The United States is seeking the federal share of Medicaid damages for the vast majority of states[1] and the District of Columbia (hereinafter collectively referred to as the "Covered States"). Federal regulations require that the payment by state Medicaid programs for drugs not subject to the FUL, not exceed, in the aggregate, the EAC of the drug, plus a reasonable dispensing fee. (US-C-SF ¶ 22) EAC is defined as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacture or labeler in the package size of drug most frequently purchased by providers." (*Id.*)

[1] The United States is not seeking Medicaid damages for the States of Arizona or Ohio, nor is the United States seeking Medicaid damages for Texas from the Dey defendants. The United States will also be moving to voluntarily dismiss its claims in connection with Arizona and Ohio.

For the period 1991 to the present, each Covered State used AWP as a component for determining EAC, during at least part of that period; forty-two (42) of the Covered States used AWP as a component for determining EAC *for the entire time period of 1991 to present*. (US-C-SF ¶ 30). The remaining Covered States used WAC or a combination of AWP and WAC as the basis for determining the EAC component of their state's drug reimbursement methodology. (US-C-SF ¶ 30).

Each of the Covered States obtained their AWP and WAC pricing from one of the major compendia (First Data, Medispan or Redbook). (US-C-SF ¶ 34). State Medicaid officials relied upon the compendia to obtain accurate, current and comprehensive pricing information to estimate acquisition costs and process their claims. (US-C-SF ¶¶ 23-24). It would have been impossible for the Medicaid programs to process the many millions of claims for reimbursement on many thousands of products, without relying on pricing information obtained from the compendia. (US-C-SF ¶ 24).

Currently all but one of the Covered States reimburses pharmacy providers for prescription drugs under a "lower of" methodology in which payment is made based, at least in part, on the lower of (1) the state's EAC plus a dispensing fee, (2) the pharmacy's usual and customary charge (U&C) (sometimes referred to as the "billed amount"), or (c) the FUL. (US-C-SF ¶ 29). With limited exception, this "lower of" methodology was followed by all Covered States for the entire period, 1991 to the present. (US-C-SF ¶ 25). At some time during the period 1991 to the present, many of the Covered States added to their "lower of" methodology a State Maximum Allowable Cost ("SMAC") feature. A SMAC is an upper limit established by the State, similar to the FUL. (US-C-SF ¶ 20).

3. Federal Payment of Medicaid Provider Claims

The Medicaid Program was established in 1965 as a joint federal and state program to provide financial assistance to individuals with low incomes to enable them to receive medical care. The state directly pays health care providers for services rendered to Medicaid recipients, with the state obtaining its federal share of the Medicaid payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 439 .0-430.30.

Congress has authorized CMS to make federal funds available to states at the beginning of each quarter based on each state's estimate on a CMS Form 37 of the likely total amount of Medicaid claims for that upcoming quarter. 42 U.S.C. § 1396b(d)(1); 42 C.F.R. § 430.30(d)(3) & (4); *see also* 42 C.F.R. § 430.30(a) & (b). The federal funds are then made available to the state which, in turn, draws on these funds through a commercial bank and the Federal Reserve system against a continuing line of credit certified to the Secretary of the Treasury in favor of the state payee. 42 C.F.R. § 430.30(d)(3) & (4); *see also* US-C-SF ¶ 87; *United States ex rel. Romano v. New York-Presbyterian Hosp.*, 2008 WL 904730 at *2 (S.D.N.Y. April 2, 2008). After each calendar quarter, the state must submit a Form 64 to CMS, a reconciliation of its actual Medicaid expenditures against the monetary advance made on the basis of the Form 37. 42 C.F.R. § 430.30(c); US-C-SF ¶ 89. The information in the Form CMS-64 is a source of information used in adjusting future Form-37 funding requests. 42 C.F.R. § 430.30(d)(2); US-C-SF ¶ 91. Since payments to the state by the federal government are adjusted as a result of these forms, they are claims presented to the United States.

IV. COMMON POINTS IN OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT AND IN SUPPORT OF THE UNITED STATES' MOTIONS WITH RESPECT TO AFFIRMATIVE DEFENSES

The United States provides this consolidated response to address common elements of defendants' damages, government knowledge, statute of limitations, and due process defenses.

A. Defendants' Summary Judgment Arguments On Damages Should Be Rejected

Because each case under the FCA involves unique types of damage to the government, there is no automatic formula by which the United States is required to calculate damages. Instead, the goal in each case is simply to estimate the damages directly caused by the filing of a false claim. *See BMY--Combat Systems Div. of Harsco Corp. v. United States*, 44 Fed.Cl. 141 (Fed.Cl.,1999); *United States ex rel. Roby v. Boeing Co.*, 79 F. Supp. 2d 877, 884-85 (S.D. Ohio 1999).

Frequently, the United States measures its damages as the difference between the amount that it paid out because of the false statements and the amount that it would have paid had the claims been truthful. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943); *United States v. Woodbury*, 359 F.2d 370, 379 (9th Cir. 1966); *United States v. Killough*, 848 F.2d 1523, 1532 (11th Cir. 1988). The United States' expert has performed calculations under this rubric by calculating the amounts actually paid by the Medicare and Medicaid programs for defendants' drugs, and then determining the amounts that would have been paid if defendants had reported truthful prices. The United States may also, however, measure damages as the full amount the government paid out on the false claims. *See United States ex rel. Anti-Discrimination Center of Metro New York v. Westchester County*, 2009 WL 1108517 (S.D.N.Y. April 24, 2009); *United*

States v. Mackby, 339 F.3d 1013 (9th Cir. 2003). The United States has pled this full measure of damages remedy and still may pursue it at trial.

In an FCA case, the United States need not prove damages with mathematical precision; it needs only to provide an adequate basis for a trier of fact to make a just and reasonable damages estimate based on the relevant data. *See United States v. Killough*, 848 F.2d at 1531; *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 263-264 (1946). In this case, to show damages, the United States needs only to demonstrate that the reimbursement for defendants' drugs would have been lower if the defendants had reported accurate prices. In the light most favorable to the United States, the evidence easily shows this to be the case, or at a minimum, that there are triable issues of fact.

1. The United States Relied on Actual Claims Data and Defendants' Own Transaction Data to Estimate Damages

Contrary to defendants' suggestions in their briefs that the United States lacks proof of actual claims or actual transactions by defendants, the United States provided defendants and its own expert in this case with multiple, complementary and often redundant, sources of state claims data and Medicare claims data, as well as defendants' own undisputed transactional data for the products listed in the complaints. (US-C-SF ¶ 116, 128, 137) Critically, the defendants do not dispute the *reliability* of the data produced by the United States and used by the United States' expert, Mark Duggan, Ph.D. Rather, they challenge the calculations he performed using that data. The weight and value of data used for damages calculations are questions for a trier of fact, however, and not appropriate for resolution on summary judgment. Nevertheless, as

demonstrated below, the data used in this case more than meets any standard for proof of damages.

a. Medicaid Data

For the state Medicaid analysis, Dr. Duggan used a combination of claims data collected directly from states and CMS. The CMS claims data, which is based on claims data submitted to CMS by the states, consists of CMS State Drug Utilization Data (SDUD), State Medicaid Research Files/Medicaid Analytic eXtract (SMRF/MAX) data, and Medicaid Statistical Information System ("MSIS") data (which is the raw data from which the SMRF/MAX data is derived). (US-C-SF ¶ 116) CMS directly collects this data from the states in connection with the operation of the Medicaid program. (US-C-SF ¶ 116) The SMRF/MAX data is *claims level data* which includes various data elements such as, for example, the NDC, date of service, charged amount, paid amount, quantity, and date of payment. (US-C-SF ¶ 116 (Henderson Common Exhibit 41 (Duggan Decl. ¶ 15)))

Without any legal or technical support whatsoever, defendants first argue that only data collected directly from states may be used to estimate damages, and that the United States cannot rely on CMS data, even in a case alleging nationwide fraud. An examination of Dr. Duggan's actual use of the data reveals the flaws in this analysis. The state data used by Dr. Duggan represents, in the aggregate, two-thirds of all Medicaid spending on the drugs alleged in the United States' complaints. Because Medicaid spending is typically highest in a small number of states, Dr. Duggan was able to cover two-thirds of the aggregate spending by using state data for 10 states in his Abbott analysis, 14 states for his Dey analysis and 16 states in his Roxane

analysis. (US-C-SF ¶ 118) Dr. Duggan then used the information from these states, together with the other CMS collected Medicaid data, to estimate damages for the remaining states. Although the SDUD, SMRF/MAX and state data all overlapped substantially, Dr. Duggan used the overlap to confirm the accuracy and reliability of his state data calculations. (US-C-SF ¶ 119, 138-157) Dr. Duggan's calculations thus included only data that was directly based upon claims submitted to the state Medicaid programs, and which he had evaluated for reliability. (US-C-SF ¶ 120)

b. Medicare Damages

Dr. Duggan used similarly reliable data sources to estimate Medicare damages. For Medicare, Dr. Duggan used: a) Medicare DME Claims Data[2] and Medicare Carrier Claims Data, and b) the price lists or "arrays" created by the Medicare carriers. As previously noted, Medicare carriers calculated reimbursement for drugs within a HCPCS code by determining a median AWP from those drugs. (US-C-SF ¶ 9-13) For each of the defendants' drugs, therefore, Dr. Duggan estimated damages by reviewing the claims processed by the Medicare carriers and identifying the median prices that would have resulted from the use of the arrays not tainted by the defendants' false prices. (US-C-SF ¶ 132-35)

In this case, as with the Medicaid damages, the defendants do not dispute the reliability of the Medicare claims data, but rather attack the completeness and variability of the underlying arrays. (Abbott SJ Br. at 16-19; Dey SJ Br. at 34-35; Roxane SJ Br. at 5-9). For Abbott, Dey

[2] For the DME carrier damages, Dr. Duggan had array information that applied to more than 90 percent of the claims during the time in which almost all of the claims were paid. (US-C-SF ¶¶ 125, 130) In the Abbott case, for regular Carriers, Dr. Duggan had array information from carrier documents for more than 3 million claims. (US-C-SF ¶ 116 (Henderson Common Exhibit 41 (Duggan Decl. ¶ 104)), ¶¶ 166-69)

and Roxane, Dr. Duggan reviewed the claims processed for the DME benefit by the DMERC carriers and calculated damages from those claims using the DMERC's arrays.

For non-DME Medicare claims for Abbott's subject drugs, Dr. Duggan performed two other types of analysis which Abbott argues were improper: 1) Where Dr. Duggan had at least *some* of the arrays, he reviewed the claims and the arrays to arrive at his damages calculation; and, 2) if arrays were not available for claims processed by the Medicare carrier, he analyzed the data in various ways to confirm that it matched the claims of the carriers for which he had arrays. (US-C-SF ¶ 159-160, 162-170) For example, Dr. Duggan's observation that Abbott's AWP was the allowed amount paid on approximately 1.3 million claims provides powerful evidence that Abbott's drugs were in the arrays used by the carriers, and that they had an effect on the median. Thus, Dr. Duggan prepared his damage estimates using a rational, articulated methodology that Abbott's expert could have replicated. (US-C-SF ¶ 128-135) Because Abbott apparently did not ask its expert in this area to prepare any competing calculations, at a minimum, a factual dispute exists precluding the entry of summary judgment in favor of Abbott. (US-C-SF ¶ 148)

c. Extrapolation in Calculating Damages

Extrapolation is simply a way to estimate by projecting known data, and it makes particular sense in a nationwide fraud case such as this. As this Court recently held in an FCA case, extrapolation is a reasonable method for determining the number of false claims, if the statistical methodology is appropriate. *See United States ex rel. Loughren v. Unumprovident Corp*., 604 F. Supp. 2d 259 (D. Mass. 2009). Estimates based on representative sampling can be used when a precise computation is technically possible but logistically impossible. *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 239 (D.P.R. 2000); *see also, Illinois Physicians*

Union v. Miller, 675 F.2d 151, 155 (7th Cir.1982) Further, failure to include all possible factors in a reasonable estimation of damages is not fatal. *United States ex rel. Tyson v. Amerigroup Illinois, Inc*., 488 F. Supp. 2d 719, 732 (N.D. Ill. 2007).

Dr. Duggan used an extremely measured factual analysis and appropriate statistical methodology in arriving at his damages opinions. See generally US-C-SF ¶ 136-170. All of Dr. Duggan's damage calculations, *even the extrapolated portions*, were rooted in actual claims data and were quite conservative. Using his methodology, Dr. Duggan determined to a reasonable degree of economic certainty damages as the difference between: (1) the amount the federal government actually reimbursed; and, (2) what the federal government would have reimbursed for the same drugs had the defendants reported their actual market prices. (US-C-SF ¶ 128) With regard to Medicaid damages, Dr. Duggan performed a claim by claim analysis of data representing two-thirds of total nationwide Medicaid utilization for the years and drugs at issue, and then used that as a basis to project the damages on the remainder of the claims. Moreover, contrary to defendants' suggestions, Dr. Duggan had state claims data, some of which was aggregate, for all states. He chose the two-thirds data primarily because it was the most complete and detailed.

Dr. Duggan's approach was very straightforward. Based on those states for which Dr. Duggan had direct state claims data (10 states for Abbott, 14 states for Dey, and 16 states for Roxane), he calculated two ratios for each NDC-Quarter: 1) the "fraudulent claims percentage" (i.e., the percentage of claims for which there was a positive difference between what the government paid and what it would have paid if the defendant had reported their actual

prices) and 2) the "fraudulent dollars percentage" (i.e., the average ratio of the difference to the amount of Medicaid spending on all claims). (US-C-SF ¶ 156) In other words, Dr. Duggan calculated the percentage of claims that were fraudulent and the percentage of money overpaid per claim. These 10, 14, and 16 states constituted between 63-68% of the total Medicaid spending for the defendants' drugs. (US-C-SF ¶ 119) To estimate the Medicaid damages for the remaining Medicaid claims and spending, Dr. Duggan calculated the averages of the "fraudulent claim percentage" and "fraudulent dollars percentage" for the 10, 14, and 16 states for each NDC-quarter and then applied those average ratios to the total claims and total Medicaid amounts paid for the remaining states by state, NDC and quarter. (US-C-SF ¶ 157)

With regard to the Medicare extrapolation, Dr. Duggan used a similar conservative methodology. For Medicare, he had complete and detailed data for all of the claims, together with the underlying "pricing arrays," for approximately two-thirds of the calculated Medicare damages. Using that information, he recalculated the amounts that would have been paid by Medicare had the pricing arrays not been tainted by inflated prices. (US-C-SF ¶ 121-127, 158-170) This analysis, combined with a conservative approach that cautiously removed several millions of claims from his calculations, was used a basis to project the damages on the remainder of the claims. In the end, the United States dropped damages for many of the claims, which obviously inured to the benefit of defendants.

In sum, defendants' contentions regarding the United States' damages methodology provide no basis on which to obtain partial summary judgment, particularly given that some of their criticism is based on steps that reduced the amount of claimed damages. Defendants fail to show whether or how Dr. Duggan's extrapolation results materially overstate the damages in

these cases. Furthermore, such a fact specific question is not suitable for summary judgment consideration. *See Parke-Davis*, 2003 WL 22048255 *5 (in response to defendant's argument on summary judgment that relator's extrapolation from a 10-doctor sample to physicians nationwide and the underlying data were both unreliable, court deferred "daunting task of determining whether a reliable statistical method exists for measuring nation-wide damages.").

d. The United States' Damage Estimates are Reliable

All three defendants contest the reliability of the United States' damages estimates, with Abbott having filed a separate *Daubert* motion in limine.[3] Because Abbott's contentions will be addressed in the United States' response to that motion, the United States will only respond to Dey and Roxane's arguments. These defendants attack Dr. Duggan's extrapolations as "inconsistent with basic statistical standards", "subject to clear selection bias", and "demonstrably unreliable."[4] However, when viewed in the light most favorable to the United States, Dr. Duggan's declaration and report are both supportable and reliable and clearly raise issues of disputed fact which preclude summary judgment.

As explained above, the extrapolation methods supporting the damages estimate here are multi-tiered: The first level analysis performed by Dr. Duggan for both the Medicare and the

[3] Pursuant to this Court's order granting the Joint Motion for Additional Briefing Schedule, the United States will address the *Daubert* related challenges set forth in Abbott's SJ Memo (at pp. 16-19) in its response to Abbott's Motion in Limine, due on October 19, 2009.

[4] Specifically, defendants complain that Dr. Duggan's selective use of data sets undermines or invalidates the work he did on arriving at a reasonable estimation of damages in this case. Abbott MSJ at 17. The use of aggregated data is routine for economists and does not diminish the reliability or validity of the damages estimates. Dr. Duggan had millions of lines of data from numerous sources. (US-C-SF ¶ 139) Dr. Duggan had data based on the actual claims submitted to each state Medicaid program for every NDC, for every year, for each defendant for which any damages are claimed, and used duplicative data to test for consistency and reliability. (US-C-SF ¶ 116-120)

Medicaid damages showed conclusively that the payments on a high percentage of claims were increased as a result of the false prices. (US-C-SF ¶ 129) For the Medicaid damages, Dr. Duggan looked at approximately two-thirds of total nationwide Medicaid utilization for the years and drugs at issue using highly detailed claims data secured directly from the state programs. *(Id.)* For the Medicare damages, Dr. Duggan looked at several million individual claims that were impacted by the arrays tainted with the defendants' false prices. (US-C-SF ¶ 166-169) The states and Medicare carriers to which he extrapolated used the same pricing data and reimbursement methodologies based on a "lower of" formula that included EAC, or the median from an array. (US-C-SF ¶ 9, 11, 29, 31-33) There can be no doubt that the false prices caused false claims to those states and carriers. (US-C-SF ¶ 25-35) The probability that the false prices caused no false claims in any of the extrapolated states or carriers is next to zero. When viewed in the light most favorable to the Government, Dr. Duggan's analysis is powerful evidence of both actual false claims and damages in the other states and carriers, and certainly precludes summary judgment.

2. Causation of Damages

There are two types of liability under the FCA, one for civil penalties and one for damages. *United States ex rel. Fago v. M & T Mortg. Corp.*, 518 F. Supp. 2d at 128. Thus, the government need not prove that the alleged false statements caused any damages to recover penalties under the Act. The FCA also mandates that the United States is entitled to recover three times "the amount of damages which the government sustains because of" the violation. 31 U.S.C. § 3729(a). Although defendants conflate the two (sometimes arguing that an absence of damages translates into an absence of false claims), defendants seek summary judgment on the

question of whether their false price reporting conduct caused the damages set forth in the expert's report and reflected in the various forms of Medicare and Medicaid payment data.

The United States contends that the "but for" test[5] applied by the Seventh Circuit in *United States v. First National Bank of Cicero*, 957 F.2d 1362, 1374 (7th Cir. 1992) is the proper standard for evaluating damages under the False Claims Act. *See Harvard*, 323 F. Supp. 2d at 185 (citing *Cicero* for proposition that "government must show that it would not have made a payment 'but for' the false statement, but need not show that subject matter of the false statement was source of the government's loss"). Defendants argue in favor of the proximate cause standard, relying heavily on *United States v. Hibbs*, 568 F.2d 347, 351 (3d Cir. 1977), which was qualified in *United States ex rel. Cantekin v. University of Pittsburgh*, 192 F.3d 402, 417 (3d Cir. 1999)(Third Circuit revisited the issue concluding that *Hibbs* cannot be applied to defeat "causation" of damages where the defendant's false statements "could have" caused the United States to not approve the payment of funds).

Regardless of which test is applied, the United States has proffered sufficient evidence to demonstrate that the government would not have paid the Medicaid claims at the inflated

[5] The courts are split as to the level of proof necessary to establish that a defendant caused damages in an FCA case. The Sixth, Seventh, and Ninth Circuits apply a pure "but for" causation test wherein "a demonstration that the government would not have [paid the claim] 'but for' the false statement is sufficient to establish the causal relationship between the false claim and the government's damages necessary to permit recovery under the False Claims Act." *Bank of Cicero*, 957 F.2d at 1374; *see also United States v. Ekelman & Associates, Inc*., 532 F.2d 545, 551 (6th Cir. 1976); *United States v. Eghbal*, 475 F. Supp. 2d 1008, 1014-15 (C.D. Cal. 2007) (citing Ninth Circuit cases). The Third, Fifth, and D.C. Circuits appear to require that the subject matter of the false statement be the source of the government's loss (this requirement has been described as a "proximate cause" standard). *Hibbs*, 568 F.2d at 351; *United States v. Miller*, 645 F.2d 473, 476 (5th Cir. 1981). Though the D.C. Circuit has approvingly cited *Hibbs*, in practice, it has applied what amounts to a "but for" causation test. *United States ex rel. Schwedt v. Planning Research Corp*., 59 F.3d 196, 200 (D.C. Cir. 1995) (holding that a contracting officer's statement that "*but for* the progress reports and representations by PRC, I would *not* have accepted and paid. . ." was sufficient to satisfy the causation requirement).

amounts had the defendants not made their false statements. (US-C-SF ¶ 128-135) The reported prices – the subject matter of the false statement – is the source of the government's loss. (US-C-SF ¶ 30-34) Similarly, as to the specific drugs cited in Dr. Duggan's report, the United States has proffered sufficient evidence to demonstrate that the Medicare Carriers would have set Medicare reimbursement for those products (and the others within the same HCPCS code) at a lower amount if the defendants had truthfully reported their prices. (US-C-SF ¶ 158-170)

Dey and Roxane contend that they are entitled to summary judgment on any claim paid on something other than the state's reimbursement methodology or even paid based on any element other than EAC, such as a FUL,[6] SMAC or U&C. (Dey SJ Br. at 26-33; Rox SJ Br. at 9-12) Under the "lower of" methodology used by the overwhelming number of states, however, the inflated AWPs and WACs are still being relied upon in the State's computerized algorithm and therefore still influence the payment to be made for the drug by the government. The issue is not whether the claim was reimbursed with the FUL or MAC or U&C amount – the issue is whether a true or accurate AWP or WAC would have resulted in lower reimbursement for a specific NDC.[7] As long as a state Medicaid program relied upon inflated prices and unnecessarily paid higher amounts, the defendants have caused injury to the government. The government's damage model is based on the simple premise that, when states paid using this

[6] The argument pertaining to FULs is exclusively advanced by Dey and Roxane as the drugs at issue in the Abbott case are not subject to FULs.

[7] The United States will not seek single FCA damages in those limited instances, if any, where a state would not have applied EAC to determine reimbursement, no matter what the defendant reported. This is different from the more common situation where a state paid on a basis other than EAC, but would have applied EAC had the defendant reported truthful prices.

lower of formula, the United States sustained damage if what the government actually paid would have been less had the defendants reported truthful prices.[8]

Second, defendants appear to be arguing that the United States needs to produce millions of claims in court to establish claims and even damages. As part and parcel of this argument, defendants argue that because Dr. Duggan did not use or have available some state claims data for certain time periods and all state claims data across the states, his opinion is inadmissible or insufficient to prove causation. As previously explained, the state and federal data used here is more than sufficient to establish both the existence of false claims and damages. Contrary to defendants' position, the submission of a "claim" does not need to be established by the actual claim. In *United States ex rel. El-Amin v. George Washington Univ.*, 522 F. Supp. 2d 135 (D.D.C. 2007), the Court found "nothing in the language of the FCA requires the actual claim form" to be presented to the factfinder." 522 F. Supp. 2d at 141-42. It is not necessary to produce evidence of every single claim submitted to the Government if, in the instant cases, there is "sufficient evidence of claim submission in general." *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F.Supp. 2d 153, 161 (D.D.C. 2008); *United States ex rel. Magid v. Wilderman*, 2004 WL 945153 (E.D. Pa. 2004); *United States v. Williams*, 216 F.3d 1099, 1103 (D.C. Cir. 2000). As to damages, a just and reasonable estimate of damages is all that is necessary, which the defendants are free to test at trial. *Bigelow*, 327 U.S. at 263-264.

[8] Because every state's reimbursement methodology relies upon AWPs or WACs to identify which of the price alternatives is the lowest, there is no genuine issue that inflated AWPs and WACs are materially ***and*** causally connected to the government's injury in these circumstances, i.e. where the reimbursement ends up being directly based upon an inflated AWP or WAC. Defendants do not challenge the materiality and causation issues in this situation.

Here, the record evidence is overwhelming that claims for payment were submitted to the United States and the defendants' assertions regarding the use of "aggregate" data go to the weight of the evidence and are not the proper subject of a motion of summary judgment. (US-C-SF ¶ 116-135) As discussed above, Dr. Duggan had both claims data obtained directly from many states and overlapping claims and payment data for all states from CMS. (*Id.*) For states or time periods in which the state did not provide Dr. Duggan with the data directly, he used data that CMS had obtained from the states. (US-C-SF ¶ 118) Moreover, it is noteworthy that not a single one of the defense experts or firms performed even a single statistical test to demonstrate that Dr. Duggan's methodology was unreliable. As a result, there are ample facts demonstrating that summary judgment for defendants is not warranted.

3. Partially Successful Mitigation Has Never Been Recognized as a Defense, and Mitigation Is Not Even Required under the FCA

The defendants' reliance on MACs, FULs or U&Cs provides no defense to liability or damages and is, at best, a mitigation issue. Mitigation of the damages by the victim naturally reduces the magnitude of the loss (but is not an "intervening cause"). Partially successful mitigation through the use of a MAC or a U&C by a state Medicaid program is not a defense to all damages, especially when the Government is not required to mitigate its FCA damages. *See, e.g., Toepleman v. United States*, 263 F.2d 697 (4th Cir. 1959); *United States ex rel. Dye v. ATK Launch Systems, Inc.*, 2008 WL 4642164 (D. Utah Oct. 16, 2008).

B. The Defendants Are Not Entitled to Summary Judgment on Unjust Enrichment

1. Under FERA, the Government's Unjust Enrichment Claim Relates Back to Relator's Complaint.

Defendants contend that the Government's claims of unjust enrichment do not relate back to relator's complaints.[9] Abbott SJ Br. at 33-39; Dey SJ Br. at n.18; Rox. SJ Br. at n.28. Since the Court's original rulings on these claims, Congress has since amended the FCA on this point – which is expressly made applicable to cases pending at the date of enactment – that mandates the reversal of the Court's previous rulings on this issue.

Congress has clarified the FCA to reflect its intent that all the Government's claims in its FCA complaints-in-intervention relate back to the relator's complaint where they arise out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in relator's complaint. Section 4(b) of FERA amends section 3731(b) of the FCA to add the following:

> (c) If the Government elects to intervene and proceed with an action brought under 3730(b), *the Government may* file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) to clarify or add detail to the claims in which the Government is intervening and to *add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person*.

[9]Defendants also make a larger argument here and in separate motions to dismiss that if the relator's complaint is barred by the public disclosure provisions of the FCA, 31 U.S.C. § 3730(e)(4), then the government's complaints-in-intervention cannot relate back to the relator's complaint. Although the United States believes there is clear Supreme Court precedent to the contrary, *see Rockwell Intern. Corp. v. United States*, 549 U.S. 457, 478 (2007), the parties have agreed to defer a response on this issue pursuant to a separate scheduling order for the motions to dismiss.

Pub. L. No. 111-21(4)(b) (emphasis added).[10] This amendment was a clarifying,[11] not substantive, change and applies "to cases pending on the date of enactment." Pub. L. No. 111-21(4)(f)(2). *See United States v. 6.93 Acres of Land*, 852 F.2d 633, 635-636 (1st Cir. 1988) (applying amendment clarifying attorney fee statute passed months after fee request was filed.).

The amended FCA § 3731 makes two points salient to the defendants' motion for summary judgment upon the unjust enrichment claims: (1) Congress intended the Government filing a complaint-in-intervention to "add *any* additional claims with respect to which the Government contends it is entitled to relief," and (2) Congress also intended that "*any* such Government pleading *shall* relate back" to the relator's complaint "to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in" the relator's complaint.

The first sentence makes clear, with its use of the comprehensive word "any," that the Government's complaint-in-intervention may include common law claims. 31 U.S.C. § 3731(c) (as amended).[12] The second sentence, using the mandatory "shall," provides that every claim in

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[10] This clarification was enacted to cure a split among courts. *Compare United States v. Baylor Univ. Med. Ctr.*, 469 F.3d 263, 268-270 (2d. Cir. 2006) (holding none of Government's claims relate back), *with In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 389, 398-401 (D. Mass. 2007) (holding FCA claims relate back but, following *Baylor,* common law claims did not), *with United States ex rel. Purcell v. MWI Corp.*, 254 F. Supp. 2d, 69, 75-76 (D.D.C. 2003) (holding that Government's FCA and common law claims relate back to relator's complaint).

[11] Section 4 of FERA is titled "Clarifications to the False Claims Act to Reflect the Original Intent of the Law." *See also Fraud Enforcement and Recovery Act of 2009* 111th Congr. at 1299 (2009); S. Rep. No. 111-10 at 10-15; *Red Lion Broad. Co. v. F.C.C.*, 395 U.S. 367, 380-81 (1969) ("Subsequent legislation declaring the intent of an earlier statute is entitled to great weight in statutory construction.") (footnote omitted).

[12] Congress was well aware that the Government frequently includes common law claims when it files complaints-in-intervention and was also aware of the split among courts on this issue. See Footnote 10, *infra*. Nevertheless, it chose the word "any" when Congress drafted the relation back clarifying amendment without limiting it to claims brought pursuant to the FCA.

the complaint-in-intervention relates back to the relator's complaint to the extent it arises out of the same conduct, transactions, or occurrences set forth in, or attempted to be set forth in, relator's complaint.[13] 31 U.S.C. § 3731(c) (as amended). In this case, the Government's unjust enrichment claims are based upon the same Abbott, Dey and Roxane conduct, transactions and occurrences alleged in the relator's complaints; they are merely alternate theories of liability. Therefore, the Government's unjust enrichment claims against Abbott, Dey and Roxane relate back to the filing of the Ven-A-Care complaint and defendants' motion for summary judgment on this point must be denied.

2. The Government Should Not Be Required to Elect its Remedy

Defendants argue that the Court should grant summary judgment upon the Government's claims for unjust enrichment on the ground that the Government cannot recover on that theory simultaneously with its legal claims. Abbott br. 38; Dey br. at 37-38; Roxane br. at n. 28. The Government should be allowed to elect its remedy at trial. *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 324 (D. Mass. 2005); *Sentinel Products Corp. v. Mobil Chemical Co.*, No. Civ.A. 98-11782, 2001 WL 92272 at *22 n.15 (D. Mass. Jan. 17, 2001).

[13] This plain reading is consistent with Congress's intent, which was to avoid forcing the Government to choose between a thorough investigation and rushing to file before the statute of limitations runs. *See* the Berman Statement at 1299 (explaining the *Baylor* court's incorrect view of relation back improperly caused the Government to rush its investigation to avoid losing claims.)

C. Defendants Cannot Establish Government Approval Sufficient for Summary Judgment and Their Related Affirmative Defenses Cannot Stand

1. "Government Knowledge" Does Not Negate The Falsity of Defendants' Price Reports Under the FCA.

Both Dey and Roxane move for summary judgment on the grounds that "government knowledge" negates falsity. As the Court has acknowledged, the weight of authority holds that, at most, government knowledge of a defendant's false or fraudulent statements may be relevant to evaluate the defendant's scienter under the FCA. Such evidence does not, however, impact falsity. *Mylan Labs*., 608 F. Supp. 2d at 148 (cases cited therein); *see also United States ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 932 (S.D. Tex. 2007)("The government's knowledge of the alleged false claim is relevant to whether the Defendant 'knowingly' submitted a false claim."); *United States ex rel. Longhi v. Lithium Power Techs., Inc*., 513 F. Supp. 2d 866, 883 (S.D. Tex. 2007) (knowledge of falsity is not enough - defendants must show "the government effectively directs the defendant to make the statement alleged to be false."), *quoting United States ex rel. Barret v. Johnson Controls, Inc*., No. 3:01-CV-1641-M, 2003 WL 21500400 (N.D. Tex. Apr. 9, 2003) (emphasis added)).

At this Court has noted, even cases finding that government knowledge may negate falsity require a showing "that the government possess knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false; some have further required that the government *actually approve* of those true facts. *Mylan Labs*., 608 F. Supp. 2d at 148 (emphasis addeed). In other words, the legal standard – full knowledge and affirmative approval – is the same whether defendants contend government knowledge negates falsity or scienter.

2. The Government Has Ample Evidence to Demonstrate that Defendants' Conduct was Knowing Under the FCA

Defendants also contend that government knowledge somehow negates scienter. This Court's recent ruling on scienter, however, should give defendants no comfort:

> Knowing that WAC was used to calculate EAC, and that EAC was meant to estimate what pharmacies actually pay for drugs, a jury could certainly conclude that the *defendants knew or were deliberately ignorant* of the fact that they were not meant to report a mere list price, a price set by manufacturers and listed at the top of invoices but almost never paid by wholesalers, but were instead meant to report a price suitable for such estimation, that is, a real price.

Mylan Labs., 608 F. Supp. 2d at 154 (first emphasis added).

To succeed on their government knowledge-based scienter argument, defendants must show that the "government [possessed] knowledge of the *actual true facts* of the claim, not simply knowledge that the claim is generally false." *Mylan Labs.*, 608 F. Supp. 2d at 148 (emphasis added). Defendants would have to show undisputed evidence that not only did they disclose the conduct at issue, but that the government formally and affirmatively approved of the alleged wrongful price reporting conduct. *See, e.g., United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) ("agency interpretations are only relevant if they are reflected in public documents . . . . The non-public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant."). Further, defendants would need unambiguous evidence that their conduct had in fact been premised on an understanding that the government had approved the conduct at issue.

a. The Government Did Not Know the Full Details and Specifics of Defendants' Price Reporting Conduct or the Actual Prices Generally and Currently Paid for Those Products

Absent from defendants' briefs is any evidence that they fully informed the federal or any state government of the relevant facts with regard to their reported prices or that any government official acted "with full knowledge of the relevant facts." Defendants must make a *particularized* showing of actual facts. *Mylan Labs.,* 608 F. Supp. 2d at 148 (emphasis added); *see also Shaw v. AAA Eng'g & Drafting, Inc*., 213 F.3d 519, 534 (10th Cir. 2000) (entertaining government knowledge defense only where government's knowledge as to the true facts is extensive). All Dey and Roxane provide are vague, self-serving statements of generalized knowledge. Dey SJ Br. at 15 (that the government knew "the same 'universe of facts' as Dey regarding the pricing for the Subject Drugs" without any evidence Dey voluntarily disclosed actual pricing information during the claims period); *see also* Rox. SJ Br. at 15 (making a similar vague claim, without factual support, government had "full knowledge" of the facts underlying reported AWPs).

Only the manufacturers, at all relevant times, had ready information about their reported prices, the prices generally and currently paid by providers for their drugs, and the manifold variations of differentials between those market prices and the prices that defendants reported to the compendia for publication. While the government does not dispute that there were numerous investigations and reports about drug reimbursement amounts in the Medicaid and Medicare programs during the relevant time period, these studies at most gave the government a general alert that there were problems, not actual knowledge of fraud by particular actors. *See generally*

Mylan Labs., 608 F. Supp. 2d at 151 ("To the contrary, the purpose of the meeting was to alert government officials to possible fraud").

Defendants rely principally on *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931 (10th Cir. 2008), a declined *qui tam* case. The holding in *Orenduff* was premised on a completely different factual scenario. The defendant in that matter echoed a governmental misclassification of the university as a "minority institution" in response to solicitations from the government for grant proposals from minority institutions. *Id.* at 947 (where Department of Defense incorrectly relied on designation by Department of Education regarding minority status, plaintiff could not show scienter on part of university officials who also relied on Department of Education designation). Defendants here cannot point to any official pronouncement by any government agency directing them to report false prices, or approving the false prices they'd already reported.

b. The Government Never Approved of Defendants' Price Reporting Conduct

Defendants never actually contend that the federal government approved of their price reporting conduct, as would be required for a government knowledge defense. As this Court correctly noted, evidence of government knowledge concerning an issue "does not support an across-the-board government knowledge defense [where] there is no evidence of government sanction." *Mylan Labs.*, 608 F. Supp. 2d at 151; *see also, United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999) ("the government's knowledge effectively negates the fraud or falsity required by the FCA" where "the government knows and approves of the particulars of a claim for payment before that claim is presented. . . .") (emphasis added); *United*

States ex rel. Butler v. Hughes Helicopters, Inc., 71 F.3d 321, 327 (9th Cir. 1995) (where the defendant and the government "so completely cooperated and shared all information," defendants' claims were not knowingly false); *United States ex rel. Longhi v. Lithium Power Techs., Inc*., 513 F. Supp. 2d at 884 ("for LPT to successfully use the defense, it must show that the government not only knew about the Army Phases I & II proposals, but that it directed LPT to disregard the solicitation instructions and not disclose the prior related work").

The closest defendants ever get to alleging actual approval is their argument that a state's implementation of MACs[14] reflects state policy to "knowingly and intentionally" pay spreads up to the level of the MAC.[15] However, this argument is belied by the state's continued implementation of a "lesser of" methodology. If the defendants were correct, the state should have also eliminated the "lesser of methodology" any time that a MAC was in place. The defendants do not and cannot show that ever happened for any state. The only discernible policy evidenced by a state's use of MACs in these cases was the state's desire to minimize the impact of the defendants' fraud, not to encourage it.

As is clear from the case law, government approval is generally very specific and tailored to the particularized conduct and individual contractor. This notion of a tacit approval of the submission of wildly inflated prices falls what short of what the law requires. Defendants have not shown any evidence of communication with any government official approving of their fraudulent price reporting. Indeed the more accurate conclusion to draw from the government

[14] Having lost on the premise that their average wholesale prices did not need to be average, wholesale or even prices, the defendants are now trying to assert that a "**Maximum**" Allowable Cost is actually a **Minimum** Allowable Cost and that a Federal **Upper** Limit is actually a Federal **Lower** Limit.

[15] The United States also notes that the defendants' ad hoc, non-regulatory, non-statutory, testimonial evidence is an insufficient basis on which to make such an evaluation.

reports and accumulated investigative knowledge is clear disapproval of the conduct at issue (perhaps most obviously illustrated by the governments' Complaints-in-Intervention in these cases). [16]

c. Defendants Did Not Rely on Any Government Approval When Reporting Their Prices

Defendants do not even attempt to show that their false price reporting was based on some understanding that the government had approved of the reporting of "sky-high prices unmoored from the acquisition costs of providers." *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d at 173. Rather, Dey and Roxane candidly admit that they set AWPs for their generic products at 10% off the brand AWPs and failed to adjust the AWP even as actual prices dropped. *See, e.g.*, L.R. 56.1 Statement of Undisputed Material Facts Applicable to Roxane Defendants ("US-BR-SF") ¶ 28; L.R. 56.1 Statement of Undisputed Material Facts Applicable to Dey Defendants ("US-D-SF") ¶¶ 84, 87. There is simply no hard evidence in the record to demonstrate that defendants actually relied on any government communication when it came to reporting prices for the drug products. Indeed, defendants simply ignored government reports raising alarm about potentially problematic price reporting conduct.

[16] As this Court previously noted, for example, OIG's Pharmaceutical Guidelines released in 2003 "defeat any notion that the federal government's failure to change the AWP pricing benchmark signaled acquiescence in spread-marketing or the reporting of mega-spreads." *In re Pharm. Indus. Average Wholesale Price Litig*, 491 F. Supp. 2d at 95. *See also In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 285 ("The weight of the legislative history reflects congressional intent to have the AWP moored to actual wholesale pricing, and a nagging concern that AWP was no longer a reasonable price."); *In re Lupron Sales Practices*, 295 F. Supp. 2d 148, 168 n. 19 (D. Mass. 2003) ("recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct").

3. The Filing of a *Qui Tam* Complaint Does Not Break the Causal Chain of an Ongoing Scheme or Establish Any Duty on the Government's Part to Mitigate Damages

Defendants also contend that the filing of a *qui tam* complaint stops them from causing damage to the United States for a fraudulent course of conduct they initiated and continue to execute. In short, they maintain that the claims period ends the day a relator files a *qui tam* complaint. This argument is premised on the notion that the Government, despite limited knowledge gleaned from the relator's complaint and disclosure statement, "cannot say it was damaged by 'reason of'" that falsity. Abbott SJ Br. at 23.

Defendants' arguments are contradicted by the structure and operation of the FCA and case law. The FCA provides for cases to be filed under seal to permit the government to conduct an investigation and determine whether to intervene, and further permits extensions of the seal period. The FCA's seal provisions were *never* designed to shield defendants from findings of liability or damages. *See United States ex rel. Harrison v. Westinghouse Savannah River* Co., 352 F.3d at 917 (identifying "instances in which a government entity might choose to continue funding the contract despite earlier wrongdoing by the contractor"); *United States v. Salti*, Case No. 1:96CV1065 (N.D. Ohio Feb. 2, 2000) (knowledge of ongoing scheme by government does not preclude recovery under the FCA)

Not surprisingly, defendants cannot cite a single FCA case that reaches this unique conclusion, relying instead on "logic." Abbott SJ Br. at 23. What defendants seek to characterize as a "causation" issue is really nothing more than a variation on the affirmative defense of failure to mitigate. As a matter of law, however, mitigation is not required in suits brought under the False Claims Act. *See, e.g., Toepleman v. United States*, 263 F.2d 697;*United States ex rel. Dye*

v. ATK Launch Systems, Inc., 2008 WL 4642164 (D. Utah Oct. 16, 2008) (defense of failure to mitigate is an improper defense to an FCA action); *United States ex rel. Jordan v. Northrop Grumman Corp.*, No. CV 95-2985 ABC at 33-35 (C.D. Cal. Aug. 6, 2002) (Exhibit ("Exh.") 1); *United States ex rel. Sanders v. Allison Engine Co.*, Case No. 1-95-970 at 4 (S.D. Ohio Apr. 9, 2002) (Exh. 2) ("[M]itigation of damages cannot be asserted as a defense in a False Claims Act case."); *United States ex rel. Ferguson v. General Dynamics Corp.*, No. 90-4703-MRP at 7-8 (C.D. Cal. Apr. 28, 1994) (Exh. 3) ("As a matter of law, General Dynamics may not assert its Seventh Affirmative Defense of 'failure to mitigate damages' against the government's claims brought under the False Claims Act."); *United States v. Consolidated Aeronautics*, No. CV 90-3408-AWT at 2 (C.D. Cal. Feb. 11, 1991) (Exh. 4) ("[A]s a matter of law under the False Claims Act, the government has no legal duty to mitigate damages"); *United States ex rel. Marcus v. Hess*, 41 F. Supp. 197 (W.D. Pa. 1941). Abbott's motion for partial summary judgment for damages that post-date the filing of relator's complaints should be denied, and the United States should be awarded partial summary judgment with respect to both Abbott and Dey's affirmative defense of failure to mitigate as it relates to claims asserted under the FCA.

4. Summary Judgment on Defendants' Government Knowledge-Based Affirmative Defenses Is Appropriate on This Record

Defendants assert several affirmative defenses that are premised on the United States' knowledge and/or conduct in administering the Medicare and Medicaid programs.[17] Many of these defenses are either insufficient as a matter of law or fall woefully short of the stringent standards imposed by the law.

[17]Roxane's Eleventh Defense is consent. Dey asserts defenses of failure to mitigate, contributory negligence and comparative fault, estoppel, waiver, and consent or ratification. Abbott asserts the following affirmative defenses: release, laches, estoppel and waiver, a failure to mitigate damages, government knowledge, and contributory or comparative fault.

a. Estoppel, Waiver, Ratification and Consent

The equitable doctrines of estoppel, waiver, and consent or ratification do not lie against the United States in this case and, accordingly, sumary judgment should be granted on the defenses. Due to the strong policy justifications for the Government's enforcement efforts, courts have consistently rejected these equitable defenses when invoked against the United States. *See, e.g., Heckler v. Community Health Services of Crawford County, Inc.,* 467 U.S. 51, 60 (1984); *Pan American Petroleum & Transport Co. v. United States*, 273 U.S. 456, 507 (1927) ("[t]he general principals of equity ... will not be applied to frustrate the purpose of [federal] laws or to thwart public policy."). The defendants should not be permitted to plead equity to avoid redressing the financial harm they caused the Medicare and Medicaid programs.

Estoppel is not available against the United States where public funds are at issue.[18] *See Rosas v. United States Small Business Admin*., 964 F.2d 351, 360 (5th Cir. 1992)(rejecting estoppel where public money was at stake)(*citing Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414 (1990)); *United States v. Walcott*, 972 F.2d 323, 327-328 (11th Cir. 1992)(same). Given that the recovery of public funds is the core function of the False Claims Act, courts have consistently stricken estoppel defenses in FCA cases. *See United States ex rel. Dye v. ATK Launch Systems, Inc.*, 2008 WL 4642164 (D. Utah Oct. 16, 2008)(logic of Supreme Court's

[18] In *OPM v. Richmond*, the Supreme Court reaffirmed long-standing precedent emphasizing that claims for estoppel cannot be entertained where public money is at stake. *Richmond*, 496 U.S. at 434. Following a review of cases involving claims of estoppel against the federal government, the Court noted that "we have reversed every finding of estoppel that we have reviewed," *id.* at 422, and that "[e]ven our recent cases evince a most strict approach to estoppel claims involving public funds." *Id.* at 426. "When the Government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined. It is for this reason that it is well settled that the Government may not be estopped on the same terms as any other litigant." *Heckler*, 467 U.S. at 60; *see also United States v. Thompson*, 749 F.2d 189, 193 (5th Cir. 1984) (the government cannot be bound by unauthorized or incorrect statements of its agents).

decision in *Richmond* applies equally in situations where the government is seeking to recover misspent public funds);*United States v. Manhattan-Westchester Med. Servs*., 2008 WL 241079 (S.D.N.Y. Jan. 28, 2008)(because civil action under FCA for Medicare and Medicaid fraud involves recovery of public funds, estoppel defense fails as a matter of law); *United States v. Cushman & Wakefield, Inc*., 275 F. Supp. 2d 763, 768 (N. D. Tex. 2002) (striking estoppel defense in FCA case). In this case, the Government seeks to recover Medicare and Medicaid damages caused by the defendants fraudulent conduct. As such, public funds are clearly at issue and an estoppel defense is unavailable.

Moreover, even where courts analyze the defense without reference to the public funds limitation, defendants are held to an extremely high standard, *see United States ex rel. Kneepkins v. Gambro Healthcare, Inc*., 115 F. Supp. 2d 35, 44 (D. Mass. 2000) (NIH advisory board recommendations carried no regulatory weight and defendants did not establish they were directed to or actually did rely on them), and have been required to establish affirmative governmental misconduct in the traditional elements of estoppel. See *Rios v. Ziglar*, 398 F.3d 1201, 1208 (10th Cir. 2005) (*citing Kowalczyk v. INS*, 245 F.3d 1143, 1149 (10th Cir. 2001))(setting for requirements for establishing estoppel including that the government must have engaged in "affirmative misconduct," and that the party asserting estoppel must have detrimentally relied upon the government's conduct). Here, despite going on at length regarding the government's perceived shortcomings in managing the Medicare and Medicaid programs, the defendants have failed to allege, must less prove, affirmative governmental misconduct.

For similar reasons, mere government acquiescence falls far short of warranting estoppel. The First Circuit specifically rejected the notion that alleged government acquiescence bars the

United States from bringing a subsequent suit. In *United States v. Michael Schiavone & Sons, Inc*., defendant sought to estop the United States from seeking treble damages based on the government's alleged suspicions about the transaction at issue and its failure to tell the defendant of the impropriety or file suit earlier. 430 F.2d 231, 232-33 (1st Cir. 1970). The court held, "[e]ven if there had been some evidence of governmental acquiescence in the 1960 sale, that would not bar the government from bringing this suit, for it is not true that once a government agency smells a rat, the agency must exterminate it forthwith or allow it the run of the public's house *in perpetuo*." *Id.* at 233.

The equitable defenses of waiver and ratification or consent, being close cousins of estoppel, also are not valid defenses in a case of this sort. As a matter of law, the Department of Justice is the only governmental body that has authority to compromise or waive the rights of the United States at issue in this suit, *see* 31 U.S.C. § 3730(a); 28 U.S.C. § 516, and the Department has done neither in this case.[19]

b. Contributory Negligence and Comparative Fault

The defenses that the United States' claims are barred by contributory negligence and comparative fault are also insufficient as a matter of law. Contributory negligence or

[19] The United States's rights may not be waived or ratified by program personnel or other government employees and may not be waived or ratified by the unauthorized acts of its agents. *See Federal Crop Insurance Corp. v. Merrill*, 332 U.S. 380, 384 (1947) (federal government not bound by the representations of its agent that are contrary to law); *Hicks v. Harris*, 606 F.2d 65, 69 (5th Cir. 1979) ("it is well established that the Government is not bound by the unauthorized or incorrect statements of its agents") (*quoting Posey v. United States*, 449 F.2d 228, 234 (5th Cir. 1971)); *see also Ferguson v. Federal Deposit Ins. Corp*., 164 F.3d 894, 899 (5th Cir. 1999) (finding affirmative defenses of waiver and ratification not applicable to United States where defendant failed to allege employee acting within scope of authority); *United States ex rel. Dye v. ATK Launch Systems*, *Inc*., 2008 WL 4642164 at *3 (D. Utah Oct. 16, 2008) (waiver defense shall be stricken in FCA case since defendant has not alleged that the Department of Justice waived these rights).

comparative fault are defenses only to actions grounded in negligence and are not defenses to an FCA action or an unjust enrichment claim. *See United States v. Aerodex, Inc.*, 469 F.2d 1003, 1009 (5th Cir. 1972) (finding that failure of Government employees to perform "100% final inspection" even where the final inspection is the obligation of the Government, does not absolve the contractor of liability under the FCA); *see also United States v. NHC Health Care Corp.*, No. 00-3128-CV-S-4-ECF, 2000 WL 33146582, *1 (W.D. Mo. Nov. 15, 2000); *United States v. Kates*, 419 F. Supp. 846, 854 (E.D. Pa. 1976) (finding contributory negligence no defense to FCA violation); *United States ex rel. Dye v. ATK Launch Systems, Inc.*, 2008 WL 4642164 (D. Utah Oct. 16, 2008); *Field v. Mans*, 516 U.S. 59, 70 (1995); *In re Mercer*, 246 F.3d 391, 421 (5th Cir. 2001). Accordingly, the affirmative defenses of contributory negligence and comparative fault are legally deficient.

D. DEFENDANTS' DUE PROCESS CLAIMS LACK MERIT

Dey and Abbott claim that the government's pre-intervention investigation of the fraudulent conduct at issue violated their due process rights and, consequently, the government should be barred from recovering the hundreds of millions of dollars in fraudulent overpayments as a result. Abbott SJ Br. at 25-32; Dey SJ Br. at 24-26. Defendants' arguments are based on false premises and inapposite case law.[20]

[20] Abbott relies principally on line of cases dealing with claims against coal companies under the the Black Lung Benefits Act. *See Lane Hollow Coal Co. v. Director, Office of Workers' Compensation Programs*, 137 F. 3d 799 (4th Cir. 1998); *Consolidated Coal Co. v. Borda*, 171 F.3d 175 (4th Cir. 1999). For example, in *Lane*, the defendant coal company and its insurer were contesting an order where the defendants had ***no*** notice of potential liability during 17 years of the pendency of the claimant's case. As discussed below, Abbott and Dey had full notice of the *qui tam* allegations and claims. Dey and Abbott both rely on *United States v. Eight Thousand Eight Hundred and Fifty Dollars*, a civil forfeiture case where the Supreme Court analyzed when a hearing in a civil forfeiture case should occur where a party has been deprived of their property. 461 U.S. 555 (1983). Unlike the *Eight Thousand* case, this case is not about defendants' being deprived of property or monies; it is about the defendants causing government monies to be spent by fraud.

Defendants note that this Court has stated that evidence of egregious delay during the pre-intervention investigation may be sufficiently prejudicial to trigger due process concerns. Abbott Memo of Law at 26. However, both Abbott and Dey ignore the Court's conclusion that, as of the date of the ruling on the Dey motion to dismiss, "Dey [had] not produced any evidence that these extensions were improper, in bad faith, or prejudice." *In re Pharm. Industry Avg. Wholesale Price Litig*., 498 F. Supp. 2d at 399.

The court in *United States ex rel. Sarmont v. Target Corp.* reviewed whether an FCA pre-intervention investigation of a similar duration (10 years) violated a defendant's due process rights. 2003 WL 22389119 (N.D.Ill. October 20, 2003). With respect to the alleged due process violations, that *Sarmont* court set forth the correct legal standard: "to show a due process violation when an action was timely filed, a defendant must demonstrate that the government intentionally delayed to gain a tactical advantage and that actual prejudice resulted." *Id., citing United States v. Marion*, 404 U.S. 307, 324 (1971). The *Sarmont* court correctly determined that the length of the investigation alone does not trigger a finding of bad faith. *Id*. at 5.

In addition, Abbott challenges the good cause extensions of the seal granted by the district court in Miami, providing a cursory summary that does more to illustrate the difficulties in getting Abbott to comply with investigative subpoenas during the investigation than to cast suspicion on the extension requests. *See* Abbott SJ Br. at 29-30. Regardless, the *Sarmont* court set forth the correct legal standard: "[a]bsent any showing that the government did not, in fact, have good cause to seek an extension of the seal period, the Court declines to revisit the California court's rulings." *Id.* at 6. Abbott's quibble with the requests amounts to no more than the "opaque 'look how long this took' arguments, which do not suggest the absence of good

cause, let alone overcome the presumption of validity accorded to" the Florida court's rulings. *Id*. at 5.

Abbott and Dey also claim that the government used the length of the pre-investigation to tactical advantage, keeping the claims at issue secret and characterizing the statutorily-mandated investigation as "one-sided discovery." Again, the *Sarmont* court addressed similar arguments and concluded:

> The Court's own review of the record reveals several factors which appear to have contributed to the prolonged investigation . . . Target's counsel was heavily engaged in discussions with the U.S. Attorney's Office . . . Target credibly submits that its interaction with the U.S. Attorney's Office was nothing more than the typical negotiating (ultimately successful) for a declination of prosecution. In any event, the parties have presented nothing which suggests that the investigative delay in this case, while undeniably significant, was due to the bad faith of any party.

Id. at 6. Abbott had ample notice to begin preparing its defenses by virtue of the extensive notice it received from the United States.[21]

Similarly, Dey was on notice of the claims and allegations as well. The Office of Inspector General for the Department of Health and Human Services (HHS-OIG) served document subpoenas on Dey in 1997 and 2000, for which Dey received and partially responded.[22]

[21] Unlike the *Lane* case Abbott relies upon, Abbott has been on notice that it was under investigation since January 1996, when it received a Civil Investigative Demand from the Department of Justice. (L.R. 56.1 Statement of Undisputed Material Facts Applicable to Abbott ("US-A-SF") ¶ 111(a)). Abbott subsequently received HHS-OIG subpoenas in 1997 and 2000. (US-A-SF ¶ 111(b)(d)) Abbott was informed of the potential claims in a detailed letter from the Justice Department sent in September 1999. (US-A-SF ¶ 111(c)) Subsequent to that letter, the government met with counsel for Abbott in October 1999 to discuss the allegations. (US-A-SF ¶ 112) Abbott also joined in an effort with multiple potential defendants to discourage the Department of Justice from intervening in the relator's case. (US-A-SF ¶ 113)

[22] As noted in the United States' Dey-specific brief, after relator filed suit under seal against Dey in Massachusetts in April 2000, alleging pricing fraud with respect to additional drugs, the United States Attorney's Office for the District of Massachusetts issued authorized investigative demands ("AIDs") for documents from Dey starting in 2000. As with the OIG subpoenas, these demands sought pricing and

Further, on October 24, 1997, the United States obtained a partial lift seal order, allowing it to disclose to Dey the substance of the allegations against Dey, met with Dey in the fall of 1998 about the allegations.[23] Any claims or intimations from Abbott or Dey that they were not on notice of the claims and/or not engaging the government about the allegations during the pre-intervention investigation in their respective cases are false.

Finally, with respect to the claims of actual prejudice, defendants provide none, relying on unsubstantiated, vague claims of document destruction and spoliation. In response to similar claims by the defendants in *Sarmont*, the court concluded:

> On the prejudice showing, a claim of prejudice must be "specific, concrete and supported by evidence." *United States v. Sowa*, 34 F.3d 447, 450 (7th Cir.1994). Here, Motorola submits that its record destruction policy likely led to the destruction of exculpatory evidence during the course of the criminal investigation, that witnesses no longer employed by Motorola may not be available to testify, and that it was not given adequate notice of the suit in order to prepare a defense. First, Motorola's arguments regarding document retention and witness availability are, at this time, entirely speculative. *See Lovasco*, 431 U.S. at 790. Second, Motorola cannot now be heard to complain that it had no notice of the pendency of a criminal investigation. It has had notice from its inception through interviews conducted in both 1990 and 1996 in the presence of Motorola counsel. Motorola's argument that, despite its knowledge of a criminal investigation into circumstances surrounding military contracts for which it was directly or indirectly involved, it did not know that it could face liability is specious.

Id at 7. Abbott and Dey's similar claims are equally specious as evidenced by the lack of specifics in their summary judgment motions and the government's arguments in its brief in opposition to the defendants' spoliation motions, filed on July 20, 2009.

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marketing information.

[23] As noted in the United States' brief in opposition to Dey's motion to dismiss, in 2000, the United States Department of Justice received a 36-page joint "white paper" prepared by Dey and other manufacturers to the Assistant Attorney General of the Civil Division, entitled "Analysis of Why the United States Should Decline Intervention in United States Ex Rel. [Relator] v. [Defendants] (S.D. Fla.).

CONCLUSION

For the reasons set forth above and in the plaintiffs' defendant-specific summary judgment briefs, plaintiffs respectfully request that the Court deny defendants' motions for summary judgment and grant plaintiffs' motions for partial summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "CONSOLIDATED MEMORANDUM IN SUPPORT OF UNITED STATES' MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO THE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Gejaa T. Gobena
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Dated: July 24, 2009